ROBERT G. DREHER
Acting Assistant Attorney General
Environment & Natural Resources Division
United States Department of Justice
LESLIE M. HILL (D.C. Bar No. 476008)
Leslie.Hill@usdoj.gov
Environmental Defense Section
601 D Street N.W., Suite 8000
Washington D.C. 20004
Telephone (202) 514-0375
Facsimile (202) 514-8865
JOHN H. MARTIN (CO Bar No. 32667)
John.H.Martin@usdoj.gov
U.S. Department of Justice
Environment & Natural Resources Division
Wildlife & Marine Resources Section
999 18th Street, South Terrace, Suite 370
Denver, CO 80202
Telephone (303) 844-1383

Attorneys for Defendants

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

STEVE ELLIS, et al.

Plaintiffs,

v.

STEVEN P. BRADBURY, in his official capacity as Director of the Office of Pesticide Programs in the United States Environmental Protection Agency, et al.

Defendants.

Case No.: 3:13-cv-1266-MMC

EPA'S NOTICE OF MOTION AND MOTION TO DISMISS

Date: November 8, 2013
Time: 9:00 am
Courtroom: 7, 19th Floor

NOTICE OF MOTION

Please take notice that on November 8, 2013 at 9:00 a.m. or as soon thereafter as counsel can be heard, Gina McCarthy,[1] in her official capacity as Administrator of the United States Environmental Protection Agency, and Steven Bradbury, in his official capacity as Director of the Office of Pesticide Programs, (collectively, "EPA") will move this Court, located in Courtroom 7, 19th Floor, United States Court House located at 450 Golden Gate Avenue, San Francisco, California, to dismiss Claim 1 in part and Claims 2-14 in their entirety.

RELIEF REQUESTED

Pursuant to Civil L. R. 7-2, EPA respectfully moves to dismiss portions of Claim 1 for lack of jurisdiction pursuant to Fed. R. Civ. Proc. 12(b)(1), Claim 2 because it is not ripe for review and for lack of jurisdiction under Fed. R. Civ. P. 12(b)(1), Claims 3-12 for failure to state a claim upon which relief can be granted under Fed. R. Civ. Proc. 12(b)(6), in the alternative, Claims 9-12 for lack of jurisdiction pursuant to Fed. R. Civ. P. 12(b)(1), and Claims 13-14 for lack of jurisdiction and failure to state a claim upon which relief can be granted under Fed. R. Civ. P. 12(b)(1) and 12(b)(6). In support of this Motion, EPA relies on the accompanying Memorandum of Points and Authorities. The relief Defendants seek is dismissal of Claim 1 in part and Claims 2-14 in their entirety.

[1] Pursuant to Fed. R. Civ. P. 25(d), Gina McCarthy is substituted for the named defendant, Robert Perciasepe, the former Acting Administrator of the EPA.

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I. INTRODUCTION

Plaintiffs' First Amended Complaint (Dkt. No. 17) (the "Complaint") seeks judicial review of EPA activities related to regulation of two pesticides, clothianidin and thiamethoxam, under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y. The Complaint presents 14 claims relating to EPA's response to a petition regarding clothianidin (Claim 1), compliance with the Endangered Species Act ("ESA") (Claims 2, 13, and 14), notice of pesticide applications and registrations and data availability upon registration (Claims 3 & 4), conditional registration conditions (Claims 5 & 6), unconditional registrations (Claims 7 & 8), suspension of registrations (Claims 9 & 10), and labeling of pesticides (Claims 11 & 12). A number of the claims include multiple elements, and many lack clarity as to the basis and scope of the claim. For the reasons set forth below, Claim 1 must be dismissed in part and Claims 2-14 must be dismissed in their entirety.

A. STATUTORY AND REGULATORY BACKGROUND

1. Federal Insecticide, Fungicide, and Rodenticide Act

FIFRA governs the sale, distribution and use of pesticides. The Act makes it unlawful, with a few minor exceptions, for any "person in any State [to] distribute or sell to any person any pesticide that is not registered" under the Act. 7 U.S.C. § 136a(a); see also 7 U.S.C. § 136j(a)(1). Thus, a registration granted by EPA under FIFRA is a license, which establishes the terms and conditions under which the pesticide may be lawfully sold, distributed, and used. See 7 U.S.C. § 136a(c)(1)(A)-(F), (d)(1).

a. Registration

Under FIFRA section 3(c)(5), EPA must register a pesticide if the Agency determines that: (A) the pesticide's composition warrants the claims to be made for it; (B) the materials, including the labeling, comply with FIFRA's requirements; (C) the intended use of the pesticide will not cause "unreasonable adverse effects on the environment;" and (D) when used "in accordance with widespread and commonly recognized practice," the pesticide will not cause unreasonable adverse effects on the environment. 7 U.S.C. §§ 136a(c)(5)(A)-(D).

"Unreasonable adverse effects on the environment" means "(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide . . .." 7 U.S.C. § 136(bb).

EPA must promptly publish notice of applications for registration if the pesticide "contains any new active ingredient or if it would entail a changed use pattern." 7 U.S.C. § 136a(c)(4). The agency must also publish a "notice of receipt" in the Federal Register and must publish notice and respond to public comments when an application proposes a "new use." 40 C.F.R. § 152.102. A new use is one that would (1) require the establishment of, increase in, or exemption from a residue tolerance on food under the Federal Food Drug and Cosmetic Act (FFDCA); (2) include any new aquatic, terrestrial, outdoor, or forestry use pattern for that active ingredient is currently registered for that use pattern; or (3) result in a significant increase in the level of exposure, or a change in the route of exposure, to the active ingredient of man or organisms. Id. § 152.3.

b. Conditional Registrations

FIFRA also allows EPA, under special circumstances, to register a pesticide "conditionally." 7 U.S.C. § 136a(c)(7). The statute provides for three types of conditional registration or conditional amendments: (a) applications for pesticide products that are substantially similar or identical to currently registered pesticides, (b) amendments to registrations to add additional uses, and (c) applications for pesticide products containing new active ingredients. This authority allows EPA to register pesticides, in these narrow circumstances where some of the necessary data are missing, but the pesticide otherwise meets the standard for registration. Id.

c. Registration Review

Registration review mandates that EPA regularly review pesticide registrations to ensure that each pesticide continues to satisfy the statutory standard for registration, that is, the pesticide can perform its intended function without unreasonable adverse effects on human health or the environment. Specifically, section 3(g) of FIFRA requires EPA to complete its

initial review by October 1, 2022, of all pesticides registered prior to October 1, 2007, and by 15 years after the date of registration for pesticides that are registered after that date. Id. § 136a(g). Following the initial review of the pesticide, EPA must complete subsequent reviews of each registered pesticide every 15 years thereafter. Id. § 136(g)(1)(A)(iv).

d. Cancellation and Suspension of Registration

EPA can initiate action to cancel a pesticide registration if it determines that the registration does not comply with FIFRA requirements. See id. § 136d(b). Under FIFRA section 6, if it appears to EPA that a pesticide does not comply with FIFRA or, when used in accordance with widespread practices, "generally causes unreasonable adverse effects on the environment," EPA may issue a notice of its intent to either: (1) cancel the pesticide's registration or change its classification; or (2) hold a hearing to determine whether the registration should be canceled. Id. FIFRA also provides the Administrator with the authority to initiate a suspension action against the registration of a pesticide if necessary to prevent an "imminent hazard" during the time required to complete the cancellation process. See 7 U.S.C. § 136d(c)(1), see also id. § 136(*l*). The Administrator is required to issue a notice of intent to cancel a registration prior to or simultaneously with the issuance of a notice of intent to suspend the registration. Id. § 136d(c). The Administrator can also issue an emergency suspension order without issuing a notice of intent to cancel or notifying the affected registrants in emergency situations that do "not permit the Administrator to hold a hearing before suspending." Id. § 136d(c)(3). After an emergency suspension order, the registrants have a right to request an expedited hearing.[2]

e. Judicial Review

Judicial review of EPA action permitted under FIFRA is divided between the courts of appeals and district courts. Challenges to "any order issued by the Administrator following a

[2] The emergency order remains in effect during the pendency of a hearing on the order. In addition, the Administrator is required to issue a notice of intent to cancel within ninety days after the issuance of the emergency suspension order. If the emergency order is not rescinded, it remains in effect through any subsequent cancellation proceedings. 7 U.S.C. § 136d(c)(3)

public hearing" must be filed in the court of appeals for the circuit within which the challenger resides or has a place of business. 7 U.S.C. § 136n(b). A challenge to "the refusal of the Administrator to cancel or suspend a registration or to change a classification not following a hearing and other *final actions* of the Administrator not committed to the discretion of the Administrator by law" must be filed in district court. Id. § 136n(a) (emphasis added). Although "public hearing" is not a defined term under FIFRA, the Court of Appeals for the Ninth Circuit held that, in the context of § 136n, EPA's issuance of notice and receipt of written comments constitutes a "public hearing." United Farm Workers v. Administrator, 592 F.3d 1080, 1082-84 (9th Cir. 2010) ("UFW").

2. Endangered Species Act

The ESA, 16 U.S.C. §§ 1531-44, establishes a program for conserving certain species listed by the Secretaries of the Interior and Commerce as endangered or threatened species ("listed species"). Id. §§ 1531(b), 1532(6), 1532(20), 1533. The Secretary of Commerce has responsibility for listed marine species and administers the ESA through the National Marine Fisheries Service ("NMFS"). The Secretary of Interior is responsible for listed terrestrial and inland fish species and administers the ESA through the U.S. Fish & Wildlife Service ("FWS"). See id. § 1532(15); 50 C.F.R. §§ 17.11, 402.01(b).

ESA section 7 directs each federal agency to insure, in consultation with FWS or NMFS, that "any action authorized, funded, or carried out by such agency . . . is not likely to jeopardize the continued existence of" any listed species or destroy or adversely modify designated critical habitat. 16 U.S.C. § 1536(a)(2). As the statutory language indicates, the consultation requirement is triggered only by affirmative agency actions. Karuk Tribe v. U.S. Forest Svc., 681 F.3d 1006, 1020 (9th Cir. 2012) (*en banc*), cert. denied, 133 S. Ct. 1579 (2013). An "action" for purposes of consultation is defined as "all activities or programs of any kind authorized, funded, or carried out, in whole or in part, by Federal agencies in the United States or upon the high seas," including, for example, "the promulgation of regulations" or "the granting of licenses." 50 C.F.R. § 402.02. In addition, a "FIFRA action" is defined for purposes of consultation as "an action by EPA to approve, permit or authorize the sale,

distribution or use of a pesticide under" FIFRA. Id. § 402.40(c). If the agency proposing an action determines that its action "may affect" listed species or critical habitat, it must pursue either informal or formal consultation with NMFS or FWS. 50 C.F.R. §§ 402.13-402.14.

ESA Section 9 prohibits "any person subject to the jurisdiction of the United States," including a federal agency, from "tak[ing] any such species within the United States." 16 U.S.C. § 1538(a)(1)(B). "Take" under the Act is defined as "to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct." Id. § 1532 (19). Regulations implementing the ESA define "harm" to mean "an act which actually kills or injures wildlife. Such act may include significant habitat modification or degradation where it actually kills or injures wildlife by significantly impairing essential behavioral patterns, including breeding, feeding or sheltering." 50 C.F.R. § 17.3.

The ESA's citizen suit provision authorizes any person to "commence a civil suit on his own behalf . . . to enjoin any person, including the United States and any other governmental instrumentality or agency . . . who is alleged to be in violation of any provision of this chapter or regulation issued under the authority thereof." 16 U.S.C. § 1540(g)(1)(A). The citizen suit provision further states that "[t]he district courts shall have jurisdiction . . . to enforce any such provision or regulation." Id. However, statutes such as FIFRA that provide for judicial review of specific categories of agency actions exclusively in the courts of appeals take precedence over more general grants of subject matter jurisdiction to the district courts, including the ESA citizen suit provision. See Am. Bird Conservancy v. F.C.C., 545 F.3d 1190, 1193-95 (9th Cir. 2008); Ctr. for Biological Diversity v. EPA, No. 11-0293, 2013 WL 1729573, at *14-22 (N.D. Cal. Apr. 22, 2013).

B. FACTUAL BACKGROUND

EPA received a petition from environmental groups and individual beekeepers[3] captioned "Emergency Citizen Petition to the United States Environmental Protection Agency

[3] Petitioners include Jeff Anderson, Manley and Linda Bigalk, Tim Brod, Craig Byer, Cynthia Cole, Ross Conrad, James Doyle, Adam French, Tim Fulton, David Hackenberg, Paula Hendricks, Dr. Carl Korschgen, Dr. Daniel Mayer, Gary McCallister, Miles

Seeking Suspension of Registration for Clothianidin" dated March 20, 2012 (hereinafter, "the Petition"). Compl. ¶ 5, n.3, 82, & n.14 (attached as Ex. A). The Petition requested that EPA take four specific actions related to clothianidin: (1) cure clothianidin's allegedly unlawful registration; (2) prevent alleged imminent harm by suspending clothianidin's registrations and initiating special review and cancellation proceedings; (3) suspend and stop sale of allegedly misbranded clothianidin products; and (4) address ESA consultation obligations for clothianidin. Petition at 5-6. The Petition did not request that EPA take action relating to thiamethoxam. The Petition requested that EPA grant the requests "within 90 days" of the filing date. Id. at 40. Despite requesting action within 90 days, the petitioners subsequently sent a series of letters to the Agency throughout the succeeding 90 days providing supplemental information that they now complain should have been considered by the Agency, presumably within their requested 90-day response period.

On May 3, 2012, Petitioners provided a self-described "supplemental filing" in support of the Petition (the "First Supplemental Filing"). Compl. ¶ 82, n.15 (attached as Ex. B). Petitioners described the supplemental materials as "new data", id., and "information that came to light after the Petition was filed" but that supports the Petition. First Supp. Filing at 1 (emphasis added). Petitioners sent a second self-described "supplemental filing" on June 18, 2012, the last day of the requested 90-day response period (the "Second Supplemental Filing"). Compl. ¶ 82, n.15 (attached as Ex. C) (appendices omitted). This filing also included "information that came to light after the Petition was filed on March 20 and after the Petitioners submitted their first supplemental filing on May 3." Second Supp. Filing at 1 (emphasis added).

McGaughey, Cass Moore, Charles Mraz, Eloise Naylor, Michael Risk, Gus Rouse, Tim Tucker, Charles Vorisek, and Stephen Whittlesey. Plaintiff-Petitioners include Steve Ellis and Tom Theobold. Plaintiffs Jim Doan and Bill Rhodes were not Petitioners. Organizational Petitioners included the Coalition4Bees and Western Colorado Beekeepers Ass'n. Organizational Plaintiff-Petitioners include Beyond Pesticides, Center for Food Safety, International Center for Technology Assessment, and the Pesticide Action Network of North America ("PANNA") in the Complaint (Dkt. No. 1) PANNA was omitted as a Plaintiff in the First Amended Complaint (Dkt. No. 17). Neither Sierra Club nor the Center for Environmental Health were parties to the Petition.

Petitioners emphasized that the second supplemental filing "contains an **order of magnitude more information on recent major bee kills**." Id. (emphasis in original).

On July 17, 2012, EPA denied the portion of the Petition requesting immediate suspension of clothianidin registrations. Compl. ¶ 5, n.4 (the "Partial Response") (attached as Ex. D).[4] EPA stated that it was denying the Petition, in part, because "nowhere in the petition do petitioners explain how the use of clothianidin rises to the level of the FIFRA imminent hazard standard." Partial Resp. at 5. Further, EPA explained that it was denying the Petition because "the imminent hazard standard also incorporates FIFRA's unreasonable adverse effects standard, which is a 'risk-benefit' standard" and, though the Petition addresses harm, it failed to address harm weighed against clothianidin's benefits, as required by the statute. Id.

EPA published notice of the Partial Response in the Federal Register. *Clothianidin; Emergency Petition to Suspend; Notice of Availability*, 77 Fed. Reg. 44,233 (July 27, 2012). The notice also requested public comment both on the denial and the remainder of the Clothianidin Petition, providing a 60-day public comment period ending September 25, 2012. Id. EPA stated that it would "address the remaining three issues in the petition after receiving and considering public comments on the petition." Id. EPA provided the Petition and First and Second Supplemental Filings for public comment and explained that it would also determine in connection with the "review whether the comments received support the reconsideration" of the Partial Response. Id.

EPA then received a September 5, 2012 letter entitled "Sixty-Day Notice of Intent to Sue Pursuant to the Endangered Species Act regarding Registration and Use Approvals of Clothianidin and Thiamethoxam, Neonicotinoid Insecticides" (the "Notice Letter") from Peter Jenkins[5] to the Administrator of the EPA and the Secretary of the Interior asserting that EPA

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[4] EPA stated that it issued the Partial Response because it was appropriate to expedite review of and its response to the imminent hazard portion of the Petition, given the emergency nature of that request and the harm alleged. Partial Resp. at 1 (Ex. A).

[5] The Notice Letter was submitted on behalf of Center for Food Safety, Beyond Pesticides, Sierra Club, and three commercial beekeepers, Jeff Anderson, Steve Ellis, and David Hackenberg.

has failed to satisfy its ESA consultation obligations under section 7(a) regarding the registration and ongoing approval of products containing clothianidin and thiamethoxam. Compl. ¶ 82 n.19 (attached as Ex. E). The Notice Letter identifies a "non-exhaustive list" of 18 listed species that clothianidin and thiamethoxam "may affect." Id.

On September 25, 2012, Petitioners submitted comments to EPA, in response to the notice of the public comment period on the Partial Response.[6] Docket No. EPA-HQ-OPP-2012-0344 (attached as Ex. F) (appendix omitted).[7] Apparently again adding to the Petition, the letter emphasizes that Petitioners are "mak[ing] six new key points." Id. at 1 (emphasis added). This correspondence also emphasized that Petitioners' First and Second supplemental filings "consisted of information that came to light after the Petition was filed, including critical new information on how certain uses of clothianidin constitute an 'imminent hazard' to honey bees and other beneficial insects." Id. at 1. Further, on the same day, the Center for Food Safety, one of the Petitioners, provided an "additional comment" that "provides a further basis" for EPA to grant the Petition. Docket No. EPA-HQ-OPP-2012-0344, Center for Food Safety (Sep. 25, 2012) (attached as Ex. G).

Petitioners sent a letter regarding "comment and notice – risks of insecticide thiamethoxam" to EPA on October 16, 2012. Compl. ¶ 5 n.5 (attached as Ex. H). The letter did not purport to be a new petition related to thiamethoxam or another supplement to the Petition, though it did include a demand that EPA "suspend the registration of thiamethoxam products, as per the clothianidin Petition" and a threat that failing to do so would result in "administrative litigation." Id. at 1. In contrast to the Petition that was presented with a caption and entitled "Emergency Petition," the "comment and notice" letter did not state that the senders considered

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[6] Facts relied upon in this Motion are based on facts alleged in the Complaint; from public documents, such as Federal Register notices, of which the Court may take judicial notice; or material on which the Plaintiffs' Complaint necessarily relies, such as documents discussed in the Complaint. See Lee v. City of Los Angeles, 250 F.3d 668, 688 (9th Cir. 2001). Facts drawn from Plaintiffs' Complaint are assumed to be true for purposes of this Motion to Dismiss only.

[7] Documents in EPA's Public Docket No. EPA-HQ-OPP-2012-0344 are available at http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2012-0334-0015.

it to be a petition as they did with the Petition. EPA responded to the senders acknowledging receipt and stating that EPA would include the comment letter in the thiamethoxam registration review docket. Compl. ¶ 5 n.5. Thiamethoxam is currently in the reregistration review process. See *Registration Review; Pesticide Dockets Opened for Review and Comment, and Notice of Availability of Final Work Plans for Certain Pesticides*, 76 Fed. Reg. 79,173, 79,173-75 (Dec. 21, 2011) (establishing a reregistration review public docket). Plaintiffs now allege that this "comment and notice" letter was a formal request, akin to their Clothianidin Legal Petition, to suspend all registrations of thiamethoxam. Compl. ¶ 88. The Complaint was filed 12 months after the Petition was filed, but only five months after petitioners stopped supplementing the Petition on September 25, 2012 (summary chart of submission and response dates is attached as Ex. I).

II. LEGAL STANDARDS

A. Rule 12(b)(1)

The plaintiff bears the burden of demonstrating the Court's subject matter jurisdiction. Kokkonen v. Guardian Life Ins. Co. of Am., 511 U.S. 375, 377 (1994). Where subject matter jurisdiction does not exist, "the court cannot proceed at all in any cause." Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 94 (1998) (citation omitted). When the existence of subject matter jurisdiction is challenged pursuant to Fed. R. Civ. P. 12(b)(1), the reviewing court may consider evidence outside the pleadings and resolve factual disputes, if necessary, to determine whether the plaintiff has met its burden of establishing jurisdiction. Ass'n of Am. Med. Colls. v. United States, 217 F.3d 770, 778 (9th Cir. 2000).

B. Rule 12(b)(6)

Dismissal pursuant to Fed. R. Civ. P. 12(b)(6) "can be based on the lack of a cognizable legal theory or the absence of sufficient facts alleged under a cognizable legal theory." Balistreri v. Pacifica Police Dept., 901 F.2d 696, 699 (9th Cir. 1990). Dismissal should be granted where the "complaint is vague, conclusory, and general and does not set forth any material facts in support of the allegations." North Star Int'l v. Ariz. Corp. Comm'n, 720 F.2d 578, 583 (9th Cir. 1983). Although well-pleaded allegations of material fact are accepted as

true and reasonable inferences are to be drawn in favor of the plaintiff, Wyler Summit P'ship v. Turner Broad. Sys., 135 F.3d 658, 661 (9th Cir. 1998), the court need not "assume the truth of legal conclusions merely because they are cast in the form of factual allegations," Fayer v. Vaughn, 649 F.3d 1061, 1064 (9th Cir. 2011), cert. denied, 132 S. Ct. 850 (2011). The Court of Appeals has made clear that "conclusory allegations of law and unwarranted inferences are insufficient to defeat a motion to dismiss for failure to state a claim." Epstein v. Wash. Energy Co., 83 F.3d 1136, 1140 (9th Cir. 1996); see also Starr v. Baca, 652 F.3d 1202, 1216 (9th Cir. 2011), cert. denied, 132 S. Ct. 2101 (2012) ("[A]llegations in a complaint or counterclaim may not simply recite the elements of a cause of action, but must contain sufficient allegations of underlying facts to give fair notice and to enable the opposing party to defend itself effectively").

C. Review under the Administrative Procedure Act

Under the APA, a person aggrieved by agency action generally may seek review of that action in district court. 5 U.S.C. § 702. "[A]gency action" is defined to include "the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act." Id. at § 551(13). Such review extends to "[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court." Id. at § 704. Where a substantive statute independently authorizes a private right of action, the APA does not govern the claims. See Washington Toxics Coalition v. EPA, 413 F.3d 1024, 1034 (9th Cir. 2005). The APA establishes a two-pronged scheme for judicial review of agency proceedings. With respect to completed agency actions, the court may "set aside" such actions found to be arbitrary, capricious, unsupported by the record, or otherwise unlawful. 5 U.S.C. § 706(2). With respect to an agency's failure to act, a court is authorized only to "compel" such actions that have been "unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1); see Norton v. S. Utah Wilderness Alliance, 542 U.S. 55, 64 (2004) ("a claim under § 706(1) can proceed only where a plaintiff asserts that an agency failed to take a discrete agency action that it is required to take") (emphasis omitted). The "agency action" at issue must also be "final agency action." 5 U.S.C. § 704; Rattlesnake Coal. v. EPA, 509 F.3d 1095, 1103 (9th Cir. 2007).

Two conditions must be satisfied for an agency action to be final. "First, the action must mark the consummation of the agency's decision-making process--it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which rights or obligations have been determined, or from which legal consequences will flow." Bennett v. Spear, 520 U.S. 154, 177-78 (1997) (internal citations and quotations omitted); see also Fairbanks N. Star Borough v. United States Army Corps of Eng'r, 543 F.3d 586, 592 (9th Cir. 2008); City of Arcadia v. EPA, 265 F. Supp. 2d 1142, 1154 (N.D. Cal 2003) (finding that a procedure that "led up to and resulted in 'final agency action'" was not itself a final agency action subject to the APA's judicial review provision).

When a plaintiff claims that an agency has failed to take a mandatory action, or has unreasonably delayed in taking such an action, it is well-established that the only relief available to the plaintiff under the APA is an order of the court requiring the agency to take the required action. 5 U.S.C. § 706(1) ("The reviewing court shall... compel agency action unlawfully withheld or unreasonably delayed"); Norton, 542 U.S. at 62; ("The APA provides relief for a failure to act in § 706(1): 'The reviewing court shall... compel agency action unlawfully withheld or unreasonably delayed.'"); American Littoral Soc'y v. EPA, 199 F. Supp. 2d 217, 240 (D.N.J. 2002) ("The Court's power in this context is limited to compelling agency action that has been unreasonably delayed."). The well-established corollary to this rule is that once the agency takes the required action, then the claim of agency inaction or unreasonable delay is moot. E.g., Kasza v. Browner, 133 F.3d 1159, 1172 (9th Cir. 1998) (case was moot where EPA complied with statutory duty after the complaint was filed); Lone Rock Timber Co. v. United States Dep't of Interior, 842 F. Supp. 433, 438 (D. Or. 1994) ("Plaintiffs originally brought this action to compel the [Fish & Wildlife Service] to issue biological opinions on specific timber sales. Since the opinions have now been issued, those claims are moot.").

III ARGUMENT

For the foregoing reasons, Claim 1 must be dismissed in part and Claims 2-14 must be dismissed in their entirety.

A. THE FIRST AND THIRD ALLEGATIONS OF CLAIM 1 SHOULD BE DISMISSED FOR FAILURE TO STATE A CLAIM AND LACK OF JURISDICTION.

Although not entirely clear, Claim 1 appears to include at least 3 distinct causes of action:

(1) Paragraph 103 alleges that EPA's failure to consider two post-petition supplemental filings in the Partial Response was arbitrary and capricious under 5 U.S.C. § 706(2). See also Compl. ¶ 104.

(2) Paragraph 103 also alleges that EPA's final action denying the request for immediate suspension of clothianidin registrations is arbitrary and capricious under 5 U.S.C. § 706(2).

(3) Paragraph 104 alleges that EPA's failure to have presently reconsidered the Partial Response, the two post-petition supplemental filings, and/or the remainder of the Petition constitutes an unreasonable delay under 5 U.S.C. § 706(1).

The First and Third Allegations should be dismissed as discussed below.

1. The First Allegation Of Claim 1 Presented In Paragraph 103 Should Be Dismissed For Lack Of Jurisdiction.

Plaintiffs allege that EPA's failure to consider material provided after the Petitioners filed the Petition in EPA's Partial Response was in itself arbitrary and capricious. EPA received the Clothianidin Petition that demanded an expedited (90-day) response (id. ¶¶ 5, 5 n.3, 82, 103) and, in an effort to respond to that demand, decided (after consulting with Plaintiffs) not to slow its response to the imminent hazard claim in the Petition by considering supplemental materials provided twice after the Petition was filed. Proving the adage that no good deed goes unpunished, Plaintiffs challenge that determination as arbitrary and capricious.

EPA's decision not to address the two supplemental filings in the Partial Response is not a final agency decision subject to review under the APA. Rather, it was a preliminary step in the Agency's consideration of the remainder of the Petition that does not, and cannot, form the basis of an independent cause of action against EPA. The Court should dismiss this portion of Claim 1 because EPA's determination to address only the materials presented in the Petition in

the Partial Response is not a final agency action. The APA does not provide a cause of action for a failure to consider or evaluate particular information except to the extent such a failure is subsumed into a claim that the resulting final agency is arbitrary and capricious. Here, that supplemental information will be considered in EPA's response to the remainder of the Petition. To the extent any claim lies with the supplemental material, it will be with EPA's future response to the remainder of the Petition, which can be challenged exclusively in the court of appeals.

Where a claim for relief under 5 U.S.C. § 706(2) fails to challenge a final agency action, that claim must be dismissed for lack of jurisdiction under Fed. R. Civ. P. 12(b)(1). United States v. Mitchell, 445 U.S. 535, 538 (1980); Rattlesnake Coal., 509 F.3d at 1103. EPA's decision to consider only the request for suspension based upon an alleged imminent hazard on the requested expedited basis in the Partial Response, and to instead, consider the supplemental filings with the remainder of the Petition satisfies the prong of finality set forth in Bennett v. Spear, 520 U.S. at 177-78. It was not the consummation of EPA's decision-making process nor did any legal consequences flow from it. See Lujan, 497 U.S. at 882; Ukiah Valley Med. Ctr. v. FTC, 911 F.2d 261, 264 n.1 (9th Cir. 1990); Fairbanks N. Star Borough, 543 F.3d at 591. Rather, EPA's intermediate determination was procedural, not substantive. Bennett, 520 U.S. at 178. To the extent the Plaintiffs have a cognizable claim related to EPA's consideration of the supplemental material, it would relate to the Agency's future response to the remainder of the Petition. See 5 U.S.C. § 704 ("A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action.").

The Court should dismiss this portion of Claim 1 because EPA's procedural determination to address only the materials presented in the Clothianidin Petition in the Partial Response is not final action subject to review under the APA.

2. The Allegation of Unreasonable Delay in Claim 1 Should Be Dismissed For Lack Of Jurisdiction Because Final Review Is Vested Exclusively In The Court Of Appeals.

Plaintiffs allege that EPA's: (1) response to the remainder of the Petition; (2) response to the First and Second Supplemental Filings; and (3) potential reconsideration of its Partial Response have been unreasonably delayed in violation of 5 U.S.C. § 706(2). Compl. ¶ 104. This Court lacks jurisdiction because review of any final action over the remainder of the Petition, is statutorily vested in the Court of Appeals under FIFRA Section 16(b), 7 U.S.C. § 136n(b), and therefore an ancillary claim of unreasonable delay must also be reviewed in the court of appeals. FIFRA's judicial review provisions provide for both district court and court of appeals jurisdiction depending on the action at issue:

> (a) District court review
>
> Except as otherwise provided in this subchapter, the refusal of the Administrator to cancel or suspend a registration or to change a classification not following a hearing and other final actions of the Administrator not committed to the discretion of the Administrator by law are judicially reviewable by the district courts of the United States.
>
> (b) Review by court of appeals
>
> In the case of actual controversy as to the validity of any order issued by the Administrator following a public hearing, any person who will be adversely affected by such order and who had been a party to the proceedings may obtain judicial review by filing in the United States court of appeals for the circuit . . .

7 U.S.C. §§ 136n(a)-(b) (emphasis added). Here, the Administrator has not yet acted on the remainder of the Petition that requests suspension or cancellation of the registrations. However, in response to the remainder of the Petition, including Plaintiffs' supplemental filings, EPA has already conducted a "public hearing" within the meaning of FIFRA Section 16(b), 7 U.S.C. § 136n(b), by publishing a notice in the Federal Register "inviting the public to comment on the decision [to deny suspension under the Petition] and the remainder of the petition." 77 Fed. Reg. at 44,233. The public comment period closed September 25, 2012. Id.

In UFW, the Court of Appeals for the Ninth Circuit addressed the meaning of "public hearing" when it considered whether jurisdiction was proper in the district court for a challenge to a registration eligibility decision made after notice and an opportunity for public comment. 592 F.3d at 1080. The key question was whether "the Administrator of the EPA ha[d] made a

decision 'not following a hearing.'" Id. at 1082. The Court of Appeals held that the meaning of "hearing" under FIFRA Section 16(b), 7 U.S.C. § 136n(b), was satisfied by the notice and opportunity to comment afforded to the challenging "manufacturers, the growers, the environmental groups, and the Farm Workers." Id. The court therefore, concluded that jurisdiction did not lie in the district court; rather, "review of the contested decision in [UFW] should have been sought in" the court of appeals. Id. at 1083.

The question here is whether review of Plaintiffs' claim of unreasonable delay should be adjudicated in this court or in the court of appeals where any challenge to the merits of EPA's response will be adjudicated. The Court of Appeals for the Ninth Circuit has addressed that question as well, holding that "[w]here a statute commits review of final agency action to the court of appeals, any suit seeking relief that might affect the court's future jurisdiction is subject to its exclusive review." Public Utility Comm'r v. Bonneville Power Admin., 767 F.2d 622, 626 (9th Cir. 1985) (adopting Telecomm. Research & Action Ctr. v. FCC, 750 F.2d 70, 74-75 (D.C. Cir. 1984) ("TRAC")); see also Sierra Club v. Johnson, No. 08-1409, 2008 WL 3820385, at *1, n.1 (N.D. Cal. Aug. 8, 2008) (noting that the Ninth Circuit had adopted TRAC). Like the instant case, TRAC concerned a challenge to a non final agency action on the ground of unreasonable delay. 750 F.2d at 72. There, the D.C. Circuit held that "where a statute commits review of agency action to the Court of Appeals, any suit seeking relief that might affect the Circuit Court's future jurisdiction is subject to the *exclusive* review of the Court of Appeals." Id. at 75.

Likewise, review of EPA's final decision on the remainder of the Petition, including its consideration of Plaintiffs' supplemental filings, will be proper, if at all, only in the court of appeals pursuant to 7 U.S.C. § 136n(b). UFW, 592 F.3d at 1083. If and when EPA's response to the remainder of the Petition is ripe for review, this Court will not have jurisdiction to review that decision. Therefore, under Bonneville Power Admin., any allegation of undue delay by the EPA in making a decision is only reviewable in the court of appeals. 767 F.2d at 626; see also George Kabeller, Inc. v. Busey, 999 F.2d 1417, 1421-22 (11th Cir. 1993) (holding that when ultimate authority to review an action lies in the court of appeals, any unreasonable delay claim

relating to the court's prospective jurisdiction also lies in court of appeals). Accordingly, this Court lacks jurisdiction over the unreasonable delay allegation in Claim 1.

B. PLAINTIFFS' SECOND CLAIM FOR RELIEF IS NOT RIPE AND IS NOT COGNIZABLE UNDER THE ESA.

Plaintiffs' second claim for relief also challenges EPA's Partial Response. Compl. ¶¶ 106-109. Plaintiffs claim the Partial Response violates the ESA and APA because the Agency failed to undertake ESA consultation with FWS "in its final agency action denying an imminent hazard." Compl. ¶ 107. This claim for relief should be dismissed as unripe because EPA has not yet taken action on Plaintiffs' entire Petition, including the request to consider effects on ESA-listed species, and because this claim fails to state a claim under the ESA.

1. The Second Claim Is Not Ripe Because EPA Has Not Decided The Petition.

The ripeness doctrine is "drawn both from Article III limitations on judicial power and from prudential reasons for refusing to exercise jurisdiction." Nat'l Park Hospitality Ass'n v. Dep't of Interior, 538 U.S. 803, 808 (2003) (quoting Reno v. Catholic Social Servs., Inc., 509 U.S. 43, 57, n.18 (1993)). Ripeness doctrine "prevent[s] the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also . . . protect[s] the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." Abbott Labs. v. Gardner, 387 U.S. 136, 148-49 (1967), overruled on other grounds, Califano v. Sanders, 430 U.S. 99 (1977).

Four of the plaintiffs here were among those who submitted the Petition to EPA on March 20, 2012, making various requests with respect to clothianidin. Compl. ¶ 82; Ex. A[8] The Petition requested that EPA act within 90 days. Ex. A at 6. EPA initially responded on July 17, 2012, narrowly addressing just the emergency request to suspend the registration of clothianidin based on the Petitioners' arguments claiming an imminent hazard to honey bees.

[8] See supra text accompanying n.3.

Compl. ¶ 83; Ex. D at 1-2. The Partial Response stated that the Agency would respond to the entire Petition in the future, including the issues pertaining to the ESA and alleged effects of clothianidin on ESA-listed species, after allowing for notice and comment and the Agency's review of the entire docket created for the Petition, including a reconsideration of its expedited denial of the emergency suspension request. Ex. D at 1, 2, 5; 77 Fed. Reg. at 44,234. EPA has not yet issued a final decision on the Petition. Compl. ¶ 84.

Because EPA has not yet conclusively decided the Petition, but declaring that a full response is forthcoming, Plaintiffs' second claim for relief is not ripe for adjudication. Toca Prods. v. FERC, 411 F.3d 262, 266 (D.C. Cir. 2005); Clark v. Busey, 959 F.2d 808, 813 (9th Cir. 1992); Consolidation Coal Co. v. Donovan, 656 F.2d 910, 916 (3d Cir. 1981). Dismissal of the second claim as unripe would serve the interests of judicial economy because the Agency's forthcoming decision on the Petition could result in the relief Plaintiffs seek and, hence, their second claim may never require adjudication. 77 Fed. Reg. at 44,234. Deeming the second claim unripe would also avoid piecemeal, duplicative, and fact-intensive litigation, insofar as this claim seeks judicial review of substantially the same issues that Plaintiffs placed before EPA in their Petition, where EPA's final response to the Petition will also be subject to judicial review.[9] Because judicial intervention would inappropriately interfere with further administrative action by EPA; and the courts would benefit from further factual development of the issues presented in the Petition, the second claim for relief is not yet ripe for review. Ohio Forestry Ass'n v. Sierra Club, 523 U.S. 726, 733-35 (1998).

2. The Second Claim for Relief Is Not Cognizable Under the Jurisdictional Bases Cited By Plaintiffs.

Plaintiffs are vague about the jurisdictional basis and cause of action supporting their second claim for relief, alleging violations of both the ESA and section 706(2) of the APA.

[9] As described above in Part III.A.2 supra, judicial review of EPA's final action on the Petition is likely to be within the "exclusive jurisdiction" of a U.S. court of appeals because EPA has provided notice of, and sought comment on, its response to the Petition. 7 U.S.C. § 136n(b).

Compl. ¶¶ 8-11, 109. Plaintiffs generally allege jurisdiction under FIFRA section 16(a), 7 U.S.C. § 136n(a). Id. ¶¶ 8, 10-11. The second claim for relief should be dismissed for lack of jurisdiction because Plaintiffs have not alleged sufficient facts to permit Defendants or the Court to determine whether this claim satisfies the jurisdictional prerequisites for any of the three separate causes of action Plaintiffs have cited. Ctr. for Biological Diversity, 2013 WL 1729573, *14-22 (dismissing Complaint for failure to allege facts demonstrating whether claims were properly brought under FIFRA sections 16(a) or 16(b) or ESA citizen suit); Chapman v. Pier 1 Imports, 631 F.3d 939, 954-55 (9th Cir. 2011) (*en banc*) (failure to allege specific facts supporting standing as part of claim required dismissal, rejecting summary list of claimed deficiencies in defendant's store).

Certain jurisdictional defects are already plain, however, from the Complaint. The Court lacks jurisdiction over the second claim under the APA and the ESA citizen suit provision because Plaintiffs fail to satisfy the jurisdictional prerequisites for either of those causes of action. There is no jurisdiction under the ESA citizen suit provision because Plaintiffs failed to provide the required notice of their intent to challenge EPA's response to the Petition. 16 U.S.C. § 1540(g)(2)(A)(i). Nor is judicial review possible under the APA because of the availability of an adequate remedy under the ESA citizen suit, 16 U.S.C. § 1540(g), or, in certain circumstances, FIFRA section 16, 7 U.S.C. § 136n, had Plaintiffs properly invoked those causes of action.

a. An APA Cause of Action Is Unavailable.

The APA authorizes judicial review in the district courts over actions by government agencies "for which there is no other adequate remedy in a court." 5 U.S.C. § 704. Judicial review of agency action under the APA is unavailable where such action may be challenged through an ESA citizen suit. Bennett, 520 U.S. at 162; Coos Cty. Bd. of Cty. Com'rs v. Kempthorne, 531 F.3d 792, 802, 810 (9th Cir. 2008) (quoting Brem-Air Disposal v. Cohen, 156 F.3d 1002, 1005 (9th Cir. 1998)); see also Oregon Natural Res. Council v. United States Forest Svc., 834 F.2d 842, 851-852 (9th Cir. 1987); Hawaii Cty. Green Party v. Clinton, 124 F. Supp. 2d 1173, 1193 (D. Haw. 2000). Suits "to compel EPA to comply with the substantive

provisions of the ESA arise under the ESA citizen suit provision, and not the APA." Washington Toxics Coalition, 413 F.3d at 1034. Based on the nature of Plaintiffs' claims of substantive statutory violations by EPA, Plaintiffs might have brought an ESA citizen suit, or in certain circumstances an action under FIFRA section 16, 7 U.S.C. § 136n, to challenge EPA's compliance with the ESA. Accordingly, a separate claim for relief under the APA is not available regarding the same agency actions.

b. Plaintiffs' Have Not Properly Commenced An ESA Citizen Suit.

The ESA citizen-suit provision authorizes civil suits "to enjoin any person, including the United States and any other governmental instrumentality or agency . . . alleged to be in violation of any provision of this chapter . . ." 16 U.S.C. § 1540(g)(1)(A). The notice provision prohibits the commencement of such an action "prior to sixty days after written notice of *the violation* has been given to the Secretary, and to any alleged violator of any such provision or regulation." Id. § 1540(g)(2)(A)(i) (emphasis added). By its plain language, the ESA's citizen-suit provision limits the availability of judicial review to claims alleging discrete "violations" and does not authorize sweeping challenges to a range of unspecified agency actions. Id. As a waiver of sovereign immunity, the citizen-suit provision must "be strictly construed, in terms of its scope, in favor of the sovereign," Lane v. Pena, 518 U.S. 187, 192 (1996), and not "enlarged . . . beyond what the language requires." Ruckelshaus v. Sierra Club, 463 U.S. 680, 685-86 (1983) (citation omitted). Plaintiffs' failure to notify EPA of any specific violation arising from the Agency's Partial Response compels dismissal of those claims now for lack of jurisdiction under the ESA.

The notice must provide sufficient detail about each perceived violation "so that the Secretary or [alleged violator] could identify and attempt to abate the violation." Sw. Ctr. for Biological Diversity v. United States Bureau of Reclamation, 143 F.3d 515, 522 (9th Cir.1998) (citation omitted); Marbled Murrelet v. Babbitt, 83 F.3d 1068, 1072 (9th Cir. 1996). If sufficient notice of a specific violation is provided and the agency does not abate the violation within 60 days, a suit "may be brought in the judicial district in which the violation occurs." 16

U.S.C. § 1540(g)(3)(A). Strict compliance with the notice requirements is a mandatory precondition to suit. See Hallstrom v. Tillamook Cnty., 493 U.S. 20, 26 (1989). Because it is jurisdictional, the failure to "strictly comply" with the notice requirement acts as an "absolute bar" to bringing suit under the ESA. Sw. Ctr. for Biological Diversity, 143 F.3d at 520; Save the Yaak Comm. v. Block, 840 F.2d 714, 721 (9th Cir. 1988).

The Notice Letter, dated September 5, 2012, that Plaintiffs rely upon here contains no mention of "EPA's final agency action in denying an 'imminent hazard existed in response to Plaintiffs' Clothianidin Legal petition." Compare Compl. ¶¶ 86, 89, 107 and Ex. E. Plaintiffs' Notice Letter does not mention the Petition and makes none of the contentions Plaintiffs now advance in their second claim. This notice letter fails to identify the ESA violation asserted here or the corrective action necessary to avoid suit on this claim for relief. Notice letters "cannot be used to support later-filed ESA claims that were not mentioned in the letter." W. Watersheds Project v. Kraayenbrink, No. 05-297, 2007 WL 952013, *1 (D. Idaho Mar. 27, 2007) (citing Sw. Ctr. for Biological Diversity, 143 F.3d at 521-22); see also Ctr. for Biological Diversity v. Chertoff, No. 08-2999, 2009 WL 839042, at *4 (N.D. Cal. Mar. 30, 2009). As a result of this deficiency, Plaintiffs may not pursue their claim that EPA has failed to consult on the Petition itself in an ESA citizen suit.

Moreover, dismissal of all ESA claims in the Complaint is required because not all Plaintiffs were signatories to the Notice Letter. Plaintiffs Jim Doan, Bill Rhodes and the Center for Environmental Health provided no notice to EPA of any ESA claims. See Ex. E. The plain language of ESA section 11(g) permits "any person" to "commence a civil suit *on his own behalf*," after providing the requisite notice. 16 U.S.C. § 1540(g)(1) (emphasis added). Reading this subsection as a whole indicates that each "person" must provide notice of the alleged violation harming its interest. An entity may not provide notice on behalf of a different "person" and a "person" that fails to provide notice may not commence a civil suit on its own behalf. See, e.g., Washington Trout v. McCain Foods, Inc., 45 F.3d 1351, 1354 (9th Cir. 1995); see also Affholter v. Franklin County Water Dist., No. 07-0388, 2008 WL 4911406, at *6 (E.D. Cal. Nov. 13, 2008). Plaintiffs' unwarranted expansion of their citizen suit beyond those

providing adequate notice compels dismissal of all the ESA claims pled in this case in claims for relief two, thirteen and fourteen.

c. EPA's Expedited Denial of the Petition Request for Suspension of All Clothianidin Registrations Is Not an Agency Action Under the ESA.

Even if Plaintiffs had provided proper notice to support a claim under the ESA citizen suit, the second claim for relief still fails as a matter of law because the EPA's Partial Response is not an "affirmative act or authorization" to which ESA section 7(a)(2) applies. Karuk Tribe, 681 F.3d at 1020-21; Cal. Sportfishing, 472 F.3d at 595. Simply put, the Agency's denial of the request for suspension and cancellation of the chemicals does not equate to an affirmative conduct authorizing their use. As this Court has recently recognized in a case raising claims similar to those here, "an agency must consult under [ESA] Section 7 *only* when it makes an affirmative act or authorization." Ctr. for Biological Diversity v. EPA, No. 11-0293, 2013 WL 1729573, at *10 (N.D. Cal. Apr. 22, 2013) (quoting Karuk Tribe, 681 F.3d at 1021) (emphasis in original).

The Petition requests that EPA first suspend and then initiate Special Review proceedings to determine whether to cancel the registration of clothianidin products under FIFRA, as well as to consult under the ESA in considering whether an imminent hazard existed. Ex. A at 3-6; Compl. ¶¶ 82, 86. Plaintiffs concede, and even affirmatively allege, that in 2003 and thereafter EPA approved the registration of different pesticide uses of, and products containing, clothianidin. Compl. ¶ 79. In these circumstances, EPA's expedited denial of a request to suspend prior registrations is not an agency action under the ESA. As the Ninth Circuit has recently made clear, "[w]here private activity is proceeding pursuant to a vested right or previously issued license, an agency has no duty to consult under Section 7 if it takes no further affirmative action regarding the activity." Karuk Tribe, 681 F.3d at 1021. The EPA's Partial Response is not an affirmative action that authorizes the use of clothianidin products, or funds or carries out their use. As such, the Partial Response is not an agency action as defined in ESA section 7(a)(2).

Nor may Plaintiffs use the Petition and the EPA's Partial Response as a strategy to evade the requirement that an ESA section 7(a)(2) claim must focus on specific affirmative actions by EPA under FIFRA. Ctr. for Biological Diversity, 2013 WL 1729573, at *10, *12; see also Ctr. for Biological Diversity, 2009 WL 839042, at *5 n.2; see also Defenders of Wildlife v. Jackson, 791 F. Supp. 2d 96, 108 (D.D.C. 2011) (distinguishing EPA registration and cancellation decisions). The Ninth Circuit rejected a similar theory in Cal. Sportfishing. In that case, the petitioners alleged that the Federal Energy Regulatory Commission ("FERC") was required to consult on the effects of a license it had issued 19 years earlier. The petitioners argued that continuing private operations under the agency license amounted to an "agency action" for purposes of ESA Section 7(a)(2). The court rejected the argument, holding that the agency "action was concluded in 1980 when FERC issued the license." 472 F.3d at 598-99. FERC had the authority to impose additional conditions for the benefit of listed species; and the petitioner had expressly petitioned FERC to initiate ESA consultation, aiming to "change the manner in which the project operated." Id. at 594-96. The Court held that neither FERC's authority to amend the license, nor its denial of the petition requesting ESA consultation, amounted to a triggering action under the ESA. Id. at 594-95, 599. Plaintiffs' identical theory here that, in response to the Petition, EPA was obligated to consult over earlier actions registering thiamethoxam products and uses was directly rejected in Cal. Sportfishing for lack of an affirmative agency action. See also W. Watershed Project v. Matejko, 468 F.3d 1099, 1102 (9th Cir. 2006) (the failure to exercise regulatory authority is not agency action). The second claim for relief seeking review of the EPA's alleged denials of ESA consultation and an imminent hazard should be likewise dismissed as not stating a colorable claim for failure to consult under, or otherwise comply with, ESA section 7(a)(2).

C. CLAIMS 3 - 12 MUST BE DISMISSED FOR FAILURE TO STATE A CLAIM UPON WHICH RELIEF CAN BE GRANTED AND CLAIMS 9-12 FAIL FOR LACK OF JURISDICTION.

Claims 3 through 12 must be dismissed, all for failure to state a claim pursuant to Fed. R. Civ. P. 12(b)(6), and Claims 9 through 12 for lack of jurisdiction pursuant to Rule 12(b)(1). The Complaint presents these claims in pairs with the first being related to clothianidin and the

second related to thiamethoxam; for example, Claim 3 generally mirrors Claim 4, and so on. In an effort to minimize confusion, we discuss each pair of claims in turn, including all bases for dismissal for each pair.

1. Claims 3 and 4 (notice and data availability). In Claims 3 and 4, Plaintiffs allege that for certain clothianidin and thiamethoxam "registrations and changed use approvals," EPA has (1) issued "new use registrations without first publishing notices of application or issuance in the Federal Register, in violation of 7 U.S.C. § 136a(c)(4) and 40 C.F.R. § 152.102," Compl. ¶¶ 111, 116, and (2) failed to "make available to the public the data called for in the registration statement" within 30 days after registration pursuant to 7 U.S.C. § 136a(c)(2). Compl. ¶¶ 112, 117. The allegations of both Claims 3 and 4 fail to contain sufficient factual matter to state a claim pursuant to Fed. R. Civ. P. 8(a)(2), and therefore must be dismissed under Fed. R. Civ. P. 12(b)(6).

Under section 3(c)(4) of FIFRA, 7 U.S.C. § 136a(c)(4), EPA is required to:

> publish in the Federal Register, promptly after receipt of the statement and other data required pursuant to [7 U.S.C. § 136a(c)(1)-(2)], a notice of each application for registration of any pesticide if it contains any new active ingredient or if it would entail a changed use pattern.

7 U.S.C. § 136a(c)(4) (emphasis added). Likewise, EPA's implementing regulation, requires EPA to issue a notice of receipt for "each application for registration that contains a new active ingredient or that proposes a new use." 40 C.F.R. § 152.102 (emphasis added). A use is a "new use" if: (1) it requires a new tolerance action under the FFDCA; (2) it is a changed use pattern -- e.g., first outdoor use or first aquatic use; or (3) it may significantly increase exposure or changes the route of exposure to humans or the environment. 40 C.F.R. § 152.3. This requirement, only applies to registrations for new active ingredients or that propose a new use for a previously registered active ingredient, but does not apply, for example, to applications to register an end-use pesticide that would be "identical or substantially similar in composition and

labeling to a currently registered pesticide" under 7 U.S.C. § 136a(c)(3)(A)[10] or to changes to the registered uses that "would [not] result in a significant increase in the level of exposure, or a change in the route of exposure, to the active ingredient of man or other organisms." 40 C.F.R. § 152.3.[11]

The Complaint fails to allege that any of the identified registration actions is for a new active ingredient or a new use such that it triggers the statutory and regulatory notice provisions. The Complaint is ambiguous at best regarding whether Plaintiffs are suggesting that all listed registrations relate to a new active ingredients or new uses. Compare Compl. ¶ 111 ("registrations and changed use approvals") and ¶ 112 ("the following new use registrations"). Without any factual support for the requirement to issue notice, Plaintiffs allege that EPA registered 31 clothianidin pesticide products and 64 thiamethoxam products between 2003 and 2012 and was required to, but did not, publish notice of application receipt or registration issuance for "a number of" the 31 clothianidin products or "potentially . . . the vast majority" of the 64 thiamethoxam products. Id. ¶¶ 111-12, 116-17. Plaintiffs fail to allege a basis for applicability of the statutory or regulatory notice provisions. See Balistreri, 901 F.2d at 699 ("Dismissal can be based on . . . the absence of sufficient facts alleged under a cognizable legal theory."); North Star Int'l, 720 F.2d at 583 (affirming dismissal of a complaint described as "vague, conclusory, and general" that failed to "set forth any material facts in support of the allegations").

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[10] The Administrator may conditionally register or amend the registration of a pesticide if the Administrator determines that: (i) the pesticide and proposed use are identical or substantially similar to any currently registered pesticide and use thereof, or differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment; and (ii) approving the registration or amendment in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment. 7 U.S.C. § 136a(c)(3)(A).

[11] Solely for illustrative purposes, EPA submits the Declaration of Meredith Laws (attached as Ex. J), describing several examples of registrations identified in the Appendices and explaining why none related to a new use within the meaning of FIFRA and its implementing regulations. EPA does not submit the Declaration in order to dispute the factual allegations in the Complaint at this stage.

Plaintiffs fail to make sufficient factual allegations related to the identified registrations and even fail to unequivocally state that each identified registration even violates the statutory or regulatory requirements, falling woefully short of the pleading requirement of Rule 8(a)(2). Accordingly, these claims must be dismissed pursuant to Fed. R. Civ. P. 12(b)(6).

Further, Plaintiffs offer no facts demonstrating that EPA failed to make data available pursuant to 7 U.S.C. § 136a(c)(2). That provision requires that:

> . . . within 30 days after the Administrator registers a pesticide under this subchapter the Administrator shall make available to the public the data called for in the registration statement together with such other scientific information as the Administrator deems relevant to the Administrator's decision.

7 U.S.C. § 136a(c)(2) (emphasis added). The Complaint is devoid of any factual statement indicating that EPA failed to make the required data available within 30 days or that Plaintiffs attempted to obtain the data and determined that it was not publicly available. Rather, Plaintiffs allege simply "[o]n information and belief . . . EPA also failed to meet this requirement."

EPA's FIFRA implementing regulations provide the specific procedures for the public to request and obtain the data referred to in section 136a(c)(2). 40 C.F.R. § 152.119(c) provides subject to some exceptions not at issue here, that within 30 days after registration, the data on which the Agency based its decision to register the product will be made available for public inspection, upon request, in accordance with 40 C.F.R. Part 2." (emphasis added). EPA regulations provide specific instructions regarding how the public may obtain agency records, including pesticide registration data. See 40 C.F.R. § 2.307. Plaintiffs do not allege that EPA rejected a request to provide data to them or to anyone, nor do they make any factual allegation regarding data availability generally, let alone regarding data availability for each identified registration.

Claims 3 and 4 must therefore be dismissed for failure to state a claim upon which relief can be granted.

2. Claims 5 & 6 (conditional registrations). Though not entirely clear, Claims 5 and 6 appear to allege that EPA has been arbitrary and capricious in failing to impose "limited, reasonable period[s]" for satisfaction of unspecified "conditions" related to 23

clothianidin and 54 thiamethoxam registrations. Compl. ¶¶ 121, 125. Plaintiffs do not specify the final agency actions they challenge or the corresponding condition and time frame of the decision, referring only generally to "the adequate pollinator field study condition." Id.[12] Plaintiffs cite FIFRA section 136d(e)(1) and 40 C.F.R. §§ 152.114-15 for the arbitrary and capricious action element of the first allegation. The cited statutory basis provides for the EPA Administrator to issue a notice of intent to cancel a conditional registration "if . . . (B) at the end of the period provided for satisfaction of any condition imposed, that condition has not been met . . . " 7 U.S.C. § 136d(e)(1)(B). Thus, in order to trigger the cancellation of a conditional registration, the time frame for a particular condition for satisfaction must have passed. Yet, Plaintiffs completely fail to identify any condition with a corresponding satisfaction date that has passed. Dismissal of Claims 5 and 6 is therefore appropriate. See Balistreri, 901 F.2d at 699 (dismissal for lack of sufficient facts alleged under a cognizable legal theory is proper); North Star Int'l, 720 F.2d at 583 (same).

This pleading failure is not just procedural. For example, if the final agency action being challenged is the decision in 2003 to conditionally register thiamethoxam and impose a "limited, reasonable period" for completion of a particular condition, then Plaintiffs' claim as to that action might well be time-barred. 28 U.S.C. § 2401(a) (general six-year statute of limitations); Wind River Min. Corp. v. United States, 946 F.2d 710, 713 (9th Cir. 1991) (holding that the general statute of limitations applies to APA actions). In addition, APA

[12] As explained supra in Pt. I.A.1.b, EPA may conditionally register or amend pesticide registrations in three circumstances. 7 U.S.C. § 136a(c)(7). For example, the Administrator may conditionally register a new active ingredient "for a period reasonably sufficient for the generation and submission of required data (which are lacking because a period reasonably sufficient for generation of the data has not elapsed since the Administrator first imposed the data requirement)" if EPA determines that "use of the pesticide during such period will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest." Id. § 136a(c)(7)(C). Although somewhat unclear, EPA does not understand Plaintiffs to be challenging the initial imposition of particular conditions in registrations. If so, these claims must be dismissed for lack of jurisdiction because Plaintiffs have not identified the Agency actions being challenged.

review is administrative record review. Camp v. Pitts, 411 U.S. 138, 142 (1973); Nat'l Wildlife Fed'n v. Burford, 871 F.2d 849, 855 (9th Cir. 1989). Absent identification of the final agency action at issue, EPA cannot compile the administrative record.

Plaintiffs also obliquely cite 5 U.S.C. § 706(1) as a basis for these claims, alleging that EPA's "duty to ensure compliance with the [ ] conditional registrations has been unlawfully and unreasonably withheld." Compl. ¶¶ 122, 126. Although it is no clear what, if any, Agency actions have been withheld, it is clear that a viable claim for unreasonable delay, 5 U.S.C. § 706(1), however, requires identification of a mandatory duty and a failure to complete that duty within a reasonable time. See Norton, 542 U.S. at 64 (holding that "a claim under § 706(1) can proceed only where a plaintiff asserts that an agency failed to take a discrete agency action that it is required to take"). Here, Plaintiffs have failed to specify the particular mandatory duty and when it accrued. Thus, the unreasonable delay allegation of the claims must also be dismissed.

3. Claims 7 & 8 (unconditional registrations). Claims 7 and 8 also fail to meet the pleading standard of Rule 8(a)(2). As the United States understands these two claims, Plaintiffs appear to allege that (1) EPA's action classifying a registration as unconditional violated FIFRA and (2) EPA has registered some pesticide products in violation of the requirements of 7 U.S.C. § 136a(c)(7), which provides for conditional registrations in three circumstances.[13]

First, Paragraph 130 of the Complaint alleges deficiencies in an Agency action taken on April 22, 2010 advising Valent U.S.A. that its registration for a clothianidin product was no longer conditional. Compl. ¶ 130. Plaintiffs generally allege that some unspecified "conditional registration provisions were not fully met" and therefore, EPA's decision was arbitrary and capricious. As explained above with regard to Claims 5 and 6, Plaintiffs simply

[13] If Plaintiffs intend to allege that EPA had a mandatory duty to "convert" conditional registrations to unconditional, those claims must also be dismissed under Fed. R. Civ. P. 12(b)(6), as there is no statutory requirement for conversion. FIFRA provides only that EPA may conditionally register a pesticide "for a period reasonably sufficient for the generation and submission of required data," not that it must, at some later point, take action to "convert" the conditional registration. 7 U.S.C. § 136a(c)(7)(C).

fail to specify the essential elements of their claim (*i.e.*, at a minimum identifying the unmet condition, the satisfaction date, and the failure of the registrant to comply with the condition) sufficient to provide anything approaching fair notice of their claims against EPA.

Similarly, the remainder of the allegations in Claims 7 and 8 are insufficient. Without any explanation, Plaintiffs allege that EPA has, at some point in time, presumably in some agency action, "classified fourteen clothianidin products [ ] as unconditional despite the failure of registrants to fill existing data gaps and comply with the past conditions," and "unconditionally registered numerous thiamethoxam products despite missing data." Compl. ¶¶ 130, 135. Again without any explanation, Plaintiffs then allege in Claim 7 that "[n]one of these products otherwise meet the criteria for unconditional registration" and in Claim 8 that in some unspecified action or actions EPA classified seven products as unconditionally registered "despite the failure of registrants to fill data gaps and missing conditions." Id. ¶¶ 131, 136. The pleading fails to identify the alleged "existing data gaps," "past conditions," "missing data," or "outstanding data gaps and conditions," much less the Agency actions being challenged.

Plaintiffs have again fallen far short of the low bar required under Fed. R. Civ. P. 8(a)(2). The Court should dismiss Claims 7 and 8 for failure to state a claim upon which relief can be granted. Alternatively, having failed to identify final agency actions at issue, Claims 7 and 8 must also be dismissed for lack of jurisdiction because judicial review under the APA or FIFRA is limited to final agency actions. 5 U.S.C. § 704, 7 U.S.C. § 136n(a); [14] Norton, 542 U.S. at 64.

4. Claims 9 & 10 (suspension). Claim 9 could be read to allege that Plaintiffs requested that EPA suspend the registrations of clothianidin containing pesticides and EPA arbitrarily and capriciously refused to do so. Although the Complaint does not use the term "arbitrary and capricious," it does refer to APA section 706(1) and (2). If the claim is

[14] *Compare* APA, 5 U.S.C. § 704, *and* FIFRA, 7 U.S.C. § 136n(a). FIFRA provides for district court review of "the refusal of the Administrator to cancel or suspend a registration or to change a classification not following a hearing and other final actions of the Administrator not committed to the discretion of the Administrator by law . . .." 7 U.S.C. § 136n(a) (emphasis added).

construed in that manner, it should be dismissed as duplicative of Claim 1. The Petition requested that EPA immediately suspend the registration of clothianidin pesticides under 7 U.S.C. § 136d(c)(1), which provides for suspension if EPA determines that such "is necessary to prevent an imminent hazard . . ." Compl. ¶¶ 82, 82 n.15, 103. EPA issued a final decision declining to find an "imminent hazard" as defined in 7 U.S.C. § 136(*l*). Id. ¶¶ 83, 83 n.16, 103. Claim 1, in part, appears to challenge that Agency action as arbitrary and capricious, id. ¶ 103, despite the styling of Claim 1 as a challenge to EPA's refusal to find that the 7 U.S.C. § 136d(c)(1) suspension predicate, "an imminent hazard," existed at the time of the Partial Response. To the extent that Claim 9 challenges EPA's refusal to suspend clothianidin registrations under 7 U.S.C. § 136d(c)(1), it is duplicative of Claim 1 and should be dismissed.

If, on the other hand, Claim 9 is construed to demand suspension of clothianidin based on Plaintiffs' conclusory assertion that "[w]hen used in accordance with widespread and commonly recognized practice, clothianidin currently causes unreasonable adverse effects on the environment," then it must be dismissed for failure to state a claim under Fed. R. Civ. P. 12(b)(6). Plaintiffs identify 7 U.S.C. § 136d(b) as the basis for the allegation that EPA refused to suspend the clothianidin registrations. That section, however, does not provide a basis for suspension of registrations. Rather, it provides the Administrator with discretionary authority to issue a notice of intent either to cancel a registration or hold a hearing to determine whether to cancel or change the registration's classification if it appears to the Administrator that "when used in accordance with widespread and commonly recognized practice, [the pesticide] generally causes unreasonable adverse effects on the environment." 7 U.S.C. § 136d(b). Because this provision plainly does not provide for the suspension of registrations, only issuance of a notice of intent to cancel, Claim 9 must be dismissed. See Balistreri, 901 F.2d at 699 (dismissal pursuant to Fed. R. Civ. P. 12(b)(6) is proper for lack of a cognizable legal theory).

5. Claims 11 & 12 (labeling). Claims 11 and 12 allege that unspecified clothianidin and thiamethoxam label warnings "violate label requirements as they do not advise the farmer, applicator, or other user how to avoid the harms that the labels acknowledge and are

not 'adequate to protect health and the environment.'" Compl. ¶¶ 151, 155. This claim is loosely based on the definition of the term "misbranded." A pesticide is misbranded if:

> the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 136a(d) of this title, are adequate to protect health and the environment . . .

7 U.S.C. § 136(q)(1)(F).

Again, Plaintiffs fail to specify the final Agency action they are challenging. The provision cited relates to the misbranding of pesticides, not the Agency's decisionmaking regarding labeling. The sufficiency of labels is generally determined at the time of a registration action. FIFRA provides that "the Administrator shall register a pesticide if the Administrator determines that:

> (B) its labeling and other material required to be submitted comply with the requirements of this subchapter;
>
> * * *
>
> (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

7 U.S.C. § 136a(c)(5). Clothianidin products were first registered in 2003 and thiamethoxam products were first registered in 2000. Compl. ¶ 79. It is not clear whether Plaintiffs intend to challenge labeling statements that were approved with these original registrations or labeling statements approved at a later date in connection with other registration or amended registration decisions. This failure to identify the final action being challenged requires dismissal of these claims.

Moreover, even if a final Agency action were identified, Claims 11 and 12 fail because they do not provide any factual basis for the bald, conclusory assertion that the unspecified product or end-use labels do not meet the requirements of 7 U.S.C. § 136a(c)(5)(B) and (D).[15]

[15] Plaintiffs hint that they might be challenging EPA's enforcement of FIFRA. Compl. ¶¶ 152, 156. For purposes of this motion, the United States assumes that Plaintiffs' reference to the definition of "misbranding" in Claims 11 and 12 means they are

D. CLAIMS 13 & 14 ARE NOT COGNIZABLE UNDER THE ESA AND FAIL TO STATE A CLAIM.

1. Plaintiffs' Failure to Provide Notice of Certain ESA Claims Compels their Dismissal for Lack of Jurisdiction.

Although Plaintiffs' notice letter lists many FIFRA actions they allege EPA took in violation of the ESA, the Complaint improperly seeks to add 17 more alleged pesticide products that were not listed in their notice letter, as well as to allege future violations arising from future registration decisions. Compare Ex. E, Ex. K (list of products with no notice) and Compl. ¶¶ 100-01, 159, 164. Likewise, the Complaint also makes conclusory allegations that EPA's failures to comply with the ESA have allowed clothianidin and thiamethoxan products to "take" federally-listed species in violation of ESA section 9. Compl. ¶¶ 51 (citing 16 U.S.C. § 1538(a)(1)(B)), 162, 167, 173. Finally, the Complaint summarily alleges that EPA violated the ESA in approving label language for all the thiamethoxan and clothianidin products listed in the Complaint. Compl. ¶¶ 161, 166. The Court lacks jurisdiction over these claims because Plaintiffs' notice letter of its claims under the ESA contains no assertion that EPA is violating ESA section 9 in any respect, let alone describes the facts evidencing such violation, such as the species or geographic location. Nor does the notice letter describe any violations of ESA section 7(a)(2) in connection with EPA's FIFRA actions regarding the 17 pesticide products in Ex. K or in paragraphs 100-101, or identify any affirmative Agency action and explain why such actions violate ESA section 7(a)(2) with regard to any particular species in any particular location. Plaintiffs' "failure to strictly comply with the notice requirement acts as an absolute bar to bringing suit under the ESA" over these particular claims. Sw. Ctr. for Biological Diversity, 143 F.3d at 520; Hallstrom 493 U.S. at 26-28. The ESA citizen suit does not permit

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complaining about some pesticide products that they believe are misbranded within the meaning of 7 U.S.C. § 136(q). See also 7 U.S.C. § 136j(a)(1)(E) (unlawful to distribute or sell misbranded pesticides). To the extent Plaintiffs are inartfully challenging EPA's decision to not to take some unspecified enforcement actions for misbranding, such a claim should be dismissed on the ground that such enforcement decisions are committed to EPA's discretion by law. See Heckler v. Cheney, 470 U.S. 821, 827-35 (1985); Sierra Club v. Whitman, 268 F.3d 898, 903-05 (9th Cir. 2001).

persons "to notify in generalities and plead in specifics, thereby eliminating the purpose underlying the notice requirement." Klamath Siskiyou Wildlands Ctr. v. Macwhorter, No. 12-1900, 2013 WL 1751287, at *2 (D. Ore. Apr. 23, 2013) (quoting Natural Res. Council of Maine v. Int'l Paper Co., 424 F. Supp. 2d 235, 250 n. 18) (D. Me. 2006)); 16 U.S.C. §1540(g)(2)(A)(i). As a result of this failure of notice, the Court lacks jurisdiction under the ESA over the allegations and claims in paragraphs 100-1, 161-2, 166-7, 173 and the products in Ex. K.

2. Plaintiffs' ESA Claims Are Unsupported By Factual Allegations and Fail to State a Claim.

These same allegations--that EPA is liable for the taking of federally-listed species in violation of ESA section 9 and for injury to Plaintiffs' interests to these species--fail to state any claim or adequately allege Plaintiffs' standing because they are too general. Compl. ¶¶ 51, 162, 167, 173. The same absence of factual allegations also dooms Plaintiffs' allegations that EPA has approved labels for thiamethoxan and clothianidin products in violation of ESA section 7. Id. ¶¶ 161, 166, 172. Neither the paragraphs alleging take of, and harm to, listed species and Plaintiffs' resulting injury, nor the remainder of the Complaint, contain facts identifying any specific incidents of take of, or harm to, any listed species, especially as those terms are defined by the ESA, or even which persons are directly violating ESA section 9, if not EPA itself. 16 U.S.C. § 1538(a)(1). Such allegations are plainly required to allege standing to pursue these ESA claims, as well as to allege a plausible violation (or violations) of ESA section 9. See Lujan v. Defenders of Wildlife, 504 U.S. 555, 561-62 (1992) ("When, however, as in this case, a plaintiff's asserted injury arises from the government's allegedly unlawful regulation (or lack of regulation) of someone else, much more is needed."). Paragraphs 162 and 167 of the Complaint, even taken together with the other allegations in the Complaint, are insufficient allegations of a violation (or violations) of ESA section 9 or Plaintiffs' standing to pursue any ESA claims. Chapman, 631 F.3d at 954-55; Ctr. for Biological Diversity, 2013 WL 1729573, at *12-13, *22.

Likewise, the paragraphs summarily alleging that EPA failed to comply with the ESA "when it approved the label language" for dozens of pesticide products is insufficient to support

any ESA claims because Plaintiffs have not alleged facts that identify any affirmative Agency acts and how those specific acts affect any particular species in any particular place with respect to any specific pesticide. Compl. ¶¶ 161, 166. Likewise, the allegations in paragraphs 159 and 164 of the Complaint do not contain any facts that support the legal conclusion therein that "EPA's actions would adversely affect particular listed species." The duty to consult under section 7 applies only "before engaging in any discretionary action that may affect a listed species or critical habitat." Karuk Tribe, 681 F.3d at 1020. As this Court has recently held, "Plaintiffs must plead facts showing the specific affirmative acts or orders of the EPA that they allege with respect to each pesticide," along with the necessary facts "showing standing with respect to each pesticide." Ctr. for Biological Diversity, 2013 WL 1729573, at *22. Plaintiffs here have committed the same error identified in the Center for Biological Diversity case by lumping dozens, or perhaps hundreds, of separate claims of ESA violations together and neglecting their obligation to ground each claimed violation in a specific affirmative act or order of the EPA, and to allege facts supporting standing for each individual claim. That deficiency warrants dismissal of Claims 13 and 14 for failure to state a claim, in addition to the jurisdictional defects identified above.

IV. CONCLUSION

For the foregoing reasons, Defendants' Motion to Dismiss should be granted. The Complaint should be dismissed in its entirety, except for the second allegation of Claim 1.

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Respectfully submitted,

Date: July 31, 2013

ROBERT G. DREHER
Acting Assistant Attorney General
Environment and Natural Resources Division

/s/
LESLIE M. HILL (D.C. Bar No. 476008)
U.S. Department of Justice
Environment & Natural Resources Division
Environmental Defense Section
601 D Street N.W., Suite 8000
Washington D.C. 20004
Leslie.Hill@usdoj.gov
Telephone (202) 514-0375
Facsimile (202) 514 8865

/s/
JOHN H. MARTIN (CO Bar No. 32667)
U.S. Department of Justice
Environment & Natural Resources Division
Wildlife & Marine Resources Section
999 18th Street, South Terrace, Suite 370
Denver, CO 80202
Telephone (303) 844-1383
john.h.martin@usdoj.gov

Attorneys for Defendant